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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/399,083	09/17/1999	DAVID CALDERWOOD	BBIC-043/A	1842

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EXAMINER	
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ART UNIT	PAPER NUMBER
1624	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/399,083	CALDERWOOD ET AL.	
	Examiner	Art Unit	
	Deepak Rao	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10,11,46 and 48-52* is/are pending in the application.

4a) Of the above claim(s) *48-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 10-11, 46, 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the amendment filed on June 2, 2008.

Claims 1-8, 10-11, 46 and 48-52 are present in this application.

Election/Restrictions

The search and examination of this application is based on the elected species (as indicated previously). Claims 48-51 and the generic portion of claims 1-8, 10-11 and 46 drawn to compounds other than those falling within the above searched/expanded subgenus (as provided in the previous office action) are withdrawn from consideration as being drawn to nonelected inventions (see MPEP § 803.02).

The following rejections are maintained:

Claim Rejections - 35 USC § 112

1. Claims 1-8 and 10-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

i. In claim 1, it is recited that "or L is –NRC(O)-, -NRC(O)O-, -$S(O)_2$NR-, -C(O)NR- or –OC(O)NR-, and R_3 is substituted or unsubstituted alkyl, substituted or unsubstituted alkenyl or substituted or unsubstituted aralkyl; provided that j is 0 when L is –CH_2NR-, -C(O)NR- or –NRC(O)- and R_3 is azacycloalkyl or azaheteroaryl" (see page 5, lines 3-7):

heterocycloalkyl; or L is -NRC(O)-, -NRC(O)O-, -$S(O)_2$NR-, -C(O)NR- or -OC(O)NR-, and R_3 is substituted or unsubstituted alkyl, substituted or unsubstituted alkenyl or substituted or unsubstituted aralkyl;

provided that j is 0 when L is -CH_2NR-, -C(O)NR- or -NRC(O)- and R_3 is azacycloalkyl or azaheteroaryl;

The above recitation is very confusing. The proviso statement lacks antecedent basis because when L is -C(O)NR- or –NRC(O)-, R_3 is defined to be alkyl, alkenyl or aralkyl and therefore, it is not understood how R_3 is recited to be azacycloalkyl or azaheteroaryl. There is no basis for this in the claim. Further, the claim defines R_3 to be cycloalkyl, aromatic group, heteroaromatic group or heterocycloalkyl group (see page 5, line s1-3) and it is not clear what is intended by the recitation "R_3 is azacycloalkyl or azaheteroaryl".

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that 'the proviso was present in the application as originally filed and with respect to the terms 'azacycloalkyl' and 'azaheteroaryl', these are groups wherein the heteroaromatic or heterocyclic rings containing a nitrogen atom'. First, there was no confusion with the terms "azaheteroaryl" and "azacycloalkyl" and applicant's explanation of the terms is acknowledged. The claim first provides a definition for L (see page 3, last paragraph), followed by a definition for R_3 (see page 4, last paragraph). The definition of L (in pages 3-4, prior to the definition of R_3 in page 4) does **not** include the terms: –CH_2NR-, -C(O)NR- or –NRC(O)-. The definition of R_3 in page 4 includes 'cyclic' groups.

Alternatively, the claim provides another definition for both L and R3 (see page 4, last paragraph): "or L is **–NRC(O)-**, -NRC(O)O-, -$S(O)_2$NR-, **-C(O)NR-** or –OC(O)NR-, and

R_3 is substituted or unsubstituted alkyl, substituted or unsubstituted alkenyl or substituted or unsubstituted aralkyl". In the above recitation, L definition includes the terms "-N(R)CO)-" and "-C(O)N(R)-" and R_3 definition does **not** include any cyclic groups. The proviso statement appearing at the top of page 5 recites that: "provided that j is 0 when L is $-CH_2NR-$, -C(O)NR- or –NRC(O)- and R_3 is azacycloalkyl or azaheteroaryl". This recitation is confusing because it is not understood if applicant intends to convey that: (a) j is 0 when both L and R_3 meet the stated requirement (i.e., L is $-CH_2NR-$, -C(O)NR- or –NRC(O)- and R_3 is azacycloalkyl or azaheteroaryl); or (b) the following two are intended separately: 'j is 0 when L is $-CH_2NR-$, -C(O)NR- or –NRC(O)-' **and** 'j is 0 when R_3 is azacycloalkyl or azaheteroaryl'. The specification does not provide a clear explanation of the proviso statement. From the recited statement, it appears that the claim is directed to the meaning as explained in option (a) above - which is improper because L and R_3 are not defined together as recited in the proviso. Appropriate explanation is required.

ii. In claim 11, it is recited "L is **$-NHSO_2R-$**, -NHC(O)O- or **–NHC(O)R-**; wherein R is H, an acyl group, …". This recitation is confusing because the terms $-NHSO_2R-$ and –NHC(O)R- do not appear to represent bivalent groups because R is a monovalent substituent group such as H. For example, -NHC(O)R- is -NHCH(O) when R is H and does not represent a bivalent linking group as required for the structural formula of the claim.

Applicant submits that 'claim 11 has been amended to delete "-H" from the definition of R'. However, such amendment was not found. Claim 11 is listed in the claim listing as

"previously presented" without any markings and therefore, there are no amendments to the claim. Further, the above L definition of "L is **–NHSO$_2$R-**, … **–NHC(O)R-**" is confusing not only when 'R is H', but also when R is all the other groups "acyl, aliphatic group, aromatic group, ...'. The claim does not clearly set forth that the recited groups are bivalent such that they fit in the definition of the linking group L. The specification does not provide any explanation or examples wherein, for example, when L is –NHSO$_2$R- and R is –H, an acyl group, etc.

Further, the claim recites that " or L is –N**R**C(O)-, -N**R**C(O)O-, -S(O)$_2$N**R**-, -C(O)N**R**- or –OC(O)N**R**-" (see page 9, lines 10-11) wherein the term R is a monovalent group which may properly include the terms "-H, acyl group, etc.". Therefore, it is very confusing how the same term " R " represents a monovalent group in one place and represents a bivalent group in another.

2. Claims 1-8 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Calderwood et al., WO 98/41525. The reasons provided in the previous office action(s) are incorporated here by reference.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant first indicates that 'the arguments presented in previous responses are maintained' and further, argues that 'claim 1 has been amended to delete "hydrogen" from the definition of R_c and the term "-N(R)S(O)O-" from the definition of L'. However, the amendment to claim 1 alone is not sufficient to overcome the rejection, for the reasons provided

in the previous office action. The claims continue to generically encompass the reference disclosed genus.

As provided previously, the reference generically teaches compounds of structural formula I wherein R_3 is represented by formula (a) wherein the phenyl ring is optionally further substituted by, for example, phenoxy, phenyl-alkyl-, halo, a group $NR_{10}R_{11}$, etc.; A is, for example, -NHC(O)O- etc.; and R_5 is optionally substituted phenyl. The reference further teaches several species falling within the disclosed genus.

The instant claim 1 recites that: Ring A is substituted with one or more substituents selected from the group consisting of aromatic group, … aryloxy, R_c … wherein R_c is aryl, etc.; and claim 11 recites that: Ring A is substituted with … aliphatic group, halogen, aromatic group, … aralkyl group, … nitro, etc. Further, the definition of L of the instant claims overlaps the reference taught definition of A.

It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole i.e., as pharmaceutical therapeutic agents. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole.

3. Claims 1-8, 10-11, 46 and 52 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-63 of U.S. Patent No. 6,713,474. The reasons provided in the previous office action are incorporated here by reference.

Applicant's request to hold the rejection in abeyance until allowable claims are found in the application is acknowledged.

The following rejections are under new grounds and/or necessitated by the amendment:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1. Claim 1 recites the limitation "provided that j is 0 when L is -CH_2NR-" in page 5, line 1. There is insufficient antecedent basis for this limitation in the claim. The term -CH_2NR- has been deleted from the definition of L (see page 3).
2. Claim 3 recites the limitation "R_c is hydrogen" in page 6, line 9. There is insufficient antecedent basis for this limitation in claim 1 on which claim 3 is dependent (via claim 2). Claim 1 has been amended to delete "hydrogen" from the definition of R_c.
3. Claim 6 recites the limitation "ring A is substituted with one or more substituents selected from … **CF_3**" in line 2. There is insufficient antecedent basis for this limitation in claim

1 on which claim 6 is dependent (via claim 5). Claim 1 does not include "CF_3" or 'haloalkyl' as a substituent on ring A (see the substituent list provided in page 2).

4. Claim 6 recites the limitation "R_c is hydrogen" in page 7, line 9. There is insufficient antecedent basis for this limitation in claim 1 on which claim 6 is dependent (via claim 5). Claim 1 has been amended to delete "hydrogen" from the definition of R_c.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 10-11, 46 and 52 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-86 of U.S. Patent No. 6,660,744. Although the conflicting claims are not identical, they are not patentably distinct from each other because

the instant claims substantially overlap the reference claims. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the reference disclosed compounds and recite a subgenus around the disclosed species, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the reference disclosed compounds, i.e., as therapeutic agents.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Monday-Friday from 8:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Deepak Rao/
Primary Examiner
Art Unit 1624

September 6, 2008